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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,340	11/23/1999	Graca Raposo	255/013-US	8331

34313 7590 06/25/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/25/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,340

Applicant(s)

Raposo et al.

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 7, and 21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *notice to comply*

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and response, filed 4/09/03, has been entered.
2. Claims 1, 4, 5, 7 and 21 are pending and being acted upon.
3. The specification is objected to for the following informality. The specification continues to disclose SEQ ID NO:1 as comprising amino acids (see for example page 7, paragraph 3). Applicant's assertion in Paper No. 13, filed 7/31/02 that "SEQ ID NO.1 AND SEQ ID NO.3 comprise nucleotide sequences and amino acid sequences" is simply in error. See line <212> of the Sequence Listings which indicates that the sequences consist of DNA. Note that while a Sequence Listing may disclose the amino acid translation of a nucleotide sequence under the DNA sequence, a SEQ ID NO: itself represents either a nucleic acid or protein.
4. In view of Applicant's amendment and response, filed 4/09/03, the rejections under the first paragraph of 35 U.S.C. 112 have been withdrawn.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
6. Claims 1, 4-5, 7, and 21, stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,955 (of record), for the reasons of record as set forth in Papers No. 10 and 15, mailed 11/21/01 and 10/10/02, respectively.

Applicant's arguments, filed 4/09/03, have been fully considered but they are not persuasive. Applicant argues "Applicant claims a method that produces an immune response against a tumor antigen" and that the administration step includes both "said tumor antigen" and a "polypeptide comprising

a functional integrin binding site of lactadherin..." Thus, the claimed invention includes the step of administering both the tumor antigen and the polypeptide containing the functional binding site of lactadherin. This element absolutely is not disclosed by the '955 USP reference or the WO 95/15171 reference and the Examiner cannot maintain the rejection under 35 U.S.C. § 102(b) based on these references."

It is the Examiner's position that both references contain both of the aforementioned elements. First, both references include the administration of a "tumor antigen". MUC1 is a well-known tumor antigen, see for example, the abstract of Botelho et al. (1998) in which MUC1 is referred to as a "tumor-specific antigen". MUC1 is also a component of milk fat globule membrane, see for example the abstract of Peterson et al. (2001). Thus, the administration of milk fat globules comprises the administration of a "tumor antigen". Second, both references teach the administration of human lactadherin, also a component milk fat globules, thus, both references meet both limitations of the claims. (Note that as currently amended a "lactadherin polypeptide" need only comprise any sequence containing an RGD tripeptide).

As set forth previously, the assertion that said administration stimulates an immune response by assertedly cross-priming antigens comprises only a further characterization of a known method. Said further characterization cannot render the known method patentably distinct.

Specifically regarding the WO95/15171 reference, Applicant argues "The reference discloses administration of a single polypeptide that is expressly stated to be "unlikely to elicit toxic, immunological or allergic reactions in treated subjects." Thus, stimulation of an immune response by administering a human antigen and lactadherin polypeptide is not disclosed," and "When a claim recites the stimulation of an immune response, a reference whose purpose is to avoid an immune response cannot be cited as inherently disclosing the immune response of the claims. An element that is expressly avoided by the reference is not inherently disclosed thereby for § 102 purposes."

It is the Examiner's position that the reference teaches the administration of the purified 46 kD HMFG protein in combination with human milk fat globules (see for example, pages 19 or 22), thus the reference teaches the method of the instant claims, regardless of any asserted property of the purified 46 kD HMFG

protein.

7. Claims 1, 4-5, 7, and 21, stand rejected under 35 U.S.C. 102(b) as being anticipated by WO95/15171 (of record), for the reasons of record as set forth in Papers No. 10 and 15, mailed 11/21/01 and 10/10/02, respectively.

Applicant has not traversed this rejection separately. See the Examiner's remarks in Section 6 above.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
June 18, 2003